GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)

LOK SABHA
STARRED QUESTION NO. 358
TO BE ANSWERED ON 10TH AUGUST, 2018
BAN ON CLINICAL TRIAL

†*358. SHRI R. DHRUVA NARAYANA:

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

(a) whether the Government has imposed ban on clinical trial of patent drugs of Ayurveda, Siddha and Unani system;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Government has formulated any scheme to check the sale of poor quality Ayush drugs in the market after imposing ban on clinical trial of patent drugs of Ayush and if so, the details thereof;

(d) if not, whether the Government is considering to formulate any such scheme; and

(e) if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE(IC) OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)

(a) & (e) : A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 358 * FOR 10TH AUGUST, 2018

(a) & (b) The Government has not banned clinical trials of patent or proprietary Ayurvedic, Siddha and Unani (ASU) drugs. Rather Ministry of AYUSH has recently issued a clarification on the request of State regulators and drug manufacturers about the provisions of Rule 158-B of the Drugs & Cosmetics Rules, 1945 in respect of pilot studies that are required as proof of safety and effectiveness for grant of license to manufacture for sale certain types of ASU drugs. The term 'clinical trial' as such is not mentioned in the context of ASU drugs-related regulatory provisions under Drugs & Cosmetics Rules, 1945 and thus the question of imposing ban on the clinical trials of ASU drugs does not arise. However, in accordance with the extant legal provisions, proof of effectiveness in the form of pilot study may be required for issuing license to an intended ASU drug, if the textual rationale, published literature and textual (authoritative book-based) indications are not furnished to support the claim of use or indication of that drug.

(c) to (e) Since the Government has not banned clinical trials of patent or proprietary ASU drugs, it is neither warranted nor envisaged to formulate any new scheme or guidelines to check the sale of poor quality drugs in the market. Definitions and penalty provisions for misbranded, spurious, adulterated and substandard ASU drugs are already prescribed in the Drugs & Cosmetics Act, 1940 to enforce quality control and take action against defaulters. Compliance to quality standards and Good Manufacturing Practices (GMP) as provided in the respective pharmacopoeias and Drugs & Cosmetics Rules, 1945 is mandatory for the drug manufacturers for grant or renewal of license to manufacture ASU drugs for sale.